IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

UNITED STATES OF AMERICA	)	
	)	
v.	)	**No. 10-cr-694-RWT**
	)	
LAUREN STEVENS,	)	
	)	
Defendant.	)	

LAUREN STEVENS' MOTION UNDER FED. R. CRIM. P. 29
FOR JUDGMENT OF ACQUITTAL

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Dated: May 8, 2011

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At the conclusion of the government's case-in-chief, it has failed to present evidence sufficient to prove beyond a reasonable doubt any of the six counts against Ms. Stevens. For this reason, the Court should enter a judgment of acquittal under Fed. R. Crim. P. 29.

The government's proof falls short with regard to each of the counts:

- As to Count I, the government appears to argue that Ms. Stevens' failure to send a set of physician slide decks, in response to a voluntary request letter from FDA, constitutes concealment under 18 U.S.C. § 1512. But the government has set forth no evidence that the decks were affirmatively "concealed" from the FDA – at most, the government has shown only that they were not produced. Where the Company was under no legal compulsion (such as a subpoena) to produce the decks, and never purported to have produced them or not to have them, this does not amount to concealment under the statute. Furthermore, the government has not proven that Ms. Stevens acted with specific, corrupt intent with regard to the decks; she acted at all times in accordance with the informed advice of reputable counsel.

- Count II, alleging obstruction under 18 U.S.C. § 1519, is premised on a spreadsheet of speaker events that Ms. Stevens provided to FDA, which did not contain information on entertainment provided to speakers. This bare fact – the extent of the government's proof – does not establish obstruction where Ms. Stevens did not purport to provide information about entertainment, where she was under no legal compulsion to provide such information, and where indeed she and others did not believe FDA had even requested such information. For the same reasons, and because Ms. Stevens acted in accordance with advice of counsel, the government has not proven that Ms. Stevens acted with the requisite intent in not providing the information on entertainment.
- As to both Counts I and II, because Ms. Stevens was engaged in a *bona fide* legal representation, she is protected from conviction by the safe harbor of 18 U.S.C. § 1515(c).
- Count III alleges that a statement regarding GSK's advisory boards, which appears in the February 28, 2003, letter, is false. The government has not proven that the omission of Special Issue Boards ("SIBs") from this description was material; nor has the government shown that the omission was anything other than the result of simple mistake.
- Count IV alleges that a statement regarding payments to attendees at speaker programs, which appears in the March 28, 2003, letter, is false. The government has not proven the falsity of this statement, which was drafted by GSK's outside counsel; nor, correspondingly, has it proven that Ms. Stevens intended it to be false.

- Counts III, V, and VI allege that certain conclusions contained in the February, May, and November 2003 letters – to the effect that GSK has not developed any programs to promote Wellbutrin off-label – constitute false statements. The government has failed to prove that these conclusions – which are clearly advocacy statements – are "false" under 18 U.S.C. § 1001. The context of the letters makes clear the truthful intended meaning of the statements, and the government has set forth insufficient evidence to disprove this reasonable interpretation. Moreover, as with the obstruction counts, the government has provided no evidence that Ms. Stevens knowingly and willfully made a false statement through these conclusions, which were drafted by GSK's outside counsel.

ARGUMENT

Under Federal Rule of Criminal Procedure 29(a), "the court on the defendant's motion must enter a judgment of acquittal of any offense for which the evidence is insufficient to sustain a conviction." Fed. R. Crim. P. 29(a); *see United States v. Bonner*, 735 F. Supp. 2d 405, 406 (M.D.N.C. 2010) (granting Rule 29 motion for judgment of acquittal based on insufficient evidence). In considering a Rule 29 motion, the "determination [ ] focuses on both the elements of the offense charged and on the factual sufficiency of the evidence." *United States v. Alerre*, 430 F.3d 681, 693 n.3 (4th Cir. 2005). Although the evidence is to be "viewed in the light most favorable to the prosecution," *United States v. Collins*, 412 F.3d 515, 519 (4th Cir. 2005), a conviction can only be sustained where the evidence is "substantial." *United States v. Burgos*, 94 F.3d 849, 862 (4th Cir. 1996) (quoting *Glasser v. United States*, 315 U.S. 60, 80 (1942)). "[S]ubstantial evidence is evidence that a reasonable finder of fact could accept as adequate and

sufficient to support a conclusion of a defendant's guilt beyond a reasonable doubt." *Id.*; *see also United States v. Roe*, 575 F. Supp. 2d 690, 692 (D. Md. 2008) (granting Rule 29 motion for judgment of acquittal).

Thus, the question raised by a motion for a judgment of acquittal is whether "as a matter of law the government's evidence is insufficient 'to establish factual guilt' on the charges in the indictment." *United States v. Alvarez*, 351 F.3d 126, 129 (4th Cir. 2003) (quoting *Smalis v. Pennsylvania*, 476 U.S. 140, 144 (1986)). "[T]o avoid a Rule 29 judgment of acquittal, the government must have presented sufficient evidence to support a conviction based on reasonable inferences, as the fact finder is not entitled to make 'leaps of logic.'" *United States v. Crounsset*, 403 F. Supp. 2d 475, 479 (E.D. Va. 2005) (quoting *Evans-Smith v. Taylor*, 19 F.3d 899, 908 n.22 (4th Cir. 1994)).

If the Court reserves decision on this motion under Rule 29(b), the Court must later resolve the motion solely on the basis of the evidence at the time the ruling was reserved without consideration of any subsequent evidence that may be presented unless the motion is renewed. Fed. R. Crim. P. 29(b); *see also Bonner*, 735 F. Supp. 2d at 406.

A decision granting a Rule 29 motion is not appealable if that decision is made *before* the jury returns a verdict. The government may not appeal such a judgment of acquittal because a successful appeal reversing a judgment of acquittal entered before the jury returned a verdict would require another trial, thus creating double jeopardy. *See United States v. Martin Linen Supply Co.*, 430 U.S. 564, 569-72 (1977) (Double Jeopardy Clause bars appeal from Rule 29(c) acquittal granted before or in absence of jury verdict); *United States v. Alvarez*, 351 F.3d 126, 129-30 (4th Cir. 2003) (appeal is barred from judgment of acquittal based on sufficiency of

evidence entered prior to jury verdict).[1] This rule addresses the concern that the Court expressed from the bench that the granting of such a motion posed a risk of unnecessary use of judicial resources, as no second trial would occur if the Court finds that the motion should be granted.

I. The Government Has Not Presented Evidence Sufficient to Show that Ms. Stevens Violated 18 U.S.C. § 1512 by "Concealing" Information from FDA

Count I alleges that Ms. Stevens corruptly obstructed an official proceeding, in violation of 18 U.S.C. § 1512(c)(2), "by making false and misleading statements to FDA, and by withholding and concealing documents and other information about promotional activities by GSK for WB." Specifically, the government appears to base this count on the team's handling of slide decks provided to GSK by 40 of its speakers (including Dr. Pradko). The government has failed to prove this count for two reasons: (1) the decks were not "concealed"; and (2) Ms. Stevens did not act with the required corrupt intent.

A. Ms. Stevens Did Not "Conceal" Anything

First, the government has not established that Ms. Stevens "concealed" the decks in violation of the statute. The facts show that FDA knew GSK had thousands of speakers, and that Ms. Stevens was seeking slide decks from them. *See* Govt. Ex. 2E; Govt. Ex. 2I-a, 2I-b. Ms. Stevens provided the FDA with several letters attaching and describing various documents. The only decks provided were for individuals specially discussed in the letters (Drs. Wolkowitz, Hudziak, and Fujioka) – with no decks provided for the hundreds of other doctors, who FDA knew existed and had given promotional presentations for GSK. Nor did Ms. Stevens ever tell FDA that she had not received any decks from the doctors. In these circumstances, Ms. Stevens

[1] *Martin Linen* was decided following the trial court's entry of a verdict of acquittal under Rule 29(c), following dismissal of a hung jury. The logic of the opinion, however, makes clear that the Double Jeopardy clause similarly bars an appeal of a judgment of acquittal entered under Rule 29(a) prior to a verdict by the jury. *See Marin Linen*, 430 U.S. at 573-75 (Rule 29 recognizes no legal distinction between judge and jury with respect to the invocation of the protections of the Double Jeopardy Clause).

could have reasonably expected that the FDA would realize it had not received a full production of slide decks.

This conduct – nonproduction of decks, without any misrepresentation of doing otherwise – does not amount to "concealment." Mere nonproduction is not punishable as obstruction. *See United States v. Weiss*, 491 F.2d 460, 466 (2d Cir. 1974) (contrasting "concealment" with "mere failure to produce the documents"). Rather, affirmative conduct is required for "concealment." *See* Parties' Joint Proposed Jury Instruction No. 33 (to "conceal" "requires some act to prevent detection of some fact the defendant was required to reveal") (quoting 1 L. Sand *et al.*, Modern Federal Jury Instructions—Crim., Instr. 36-4); Sand Instr. 36-4, cmt. ("Concealment of a material fact requires more than mere nondisclosure. It requires proof of an affirmative act which actively conceals a material fact.") (citing case law under § 1001 "concealment" prong); s*ee, e.g.*, *United States v. Church*, 11 F. App'x 264, 265-66 and 268 (4th Cir. 2001) (defendant buried documents in the back yard); *United States v. Weston*, No. 91-5359, 1992 U.S. App. LEXIS 9061, at *18 (4th Cir. Apr. 30, 1992) (in avoiding response to a subpoena, defendant altered the records sought by the subpoena, provided some while concealing others, and "represented to the FBI that he did not have any further records"); *United States v. Lessner*, 498 F.3d 185 (3d Cir. 2007) (defendant threw evidence into the trash can and instructed a subordinate to tear up documents).

Moreover, "[o]rdinarily, a defendant may not be convicted of concealment unless the defendant had a duty to disclose." *United States v. Richeson*, 825 F.2d 17, 20 (4th Cir. 1987) (citing Tenth Circuit authority); *accord* Sand Instr. 36-4, cmt. ("There must be a legal duty to disclose to the government the material facts allegedly concealed.") (citing case law under § 1001 "concealment" prong). To be sure, courts have found that intentional failure to produce

documents required by a *subpoena* may be concealment. *See Weston*, 1992 U.S. App. LEXIS 9061, at *18 (finding obstruction where defendant "deliberately concealed a highly relevant portion of the subpoenaed documents with the corrupt motive of throwing the grand jury off his track"); *United States v. Ruggiero,* 934 F.2d 440, 446 (2d Cir. 1991) (finding obstruction where, *inter alia*, defendants withheld letters responsive to a grand jury subpoena). In contrast, though, research has revealed *not one decision* holding that mere failure to produce documents in response to a voluntary letter request, without more, constitutes obstruction of justice. Nor was a legal compulsion engendered by Ms. Stevens' voluntary commitment to make a "good-faith effort" to collect and provide the physicians' presentations and to notify FDA if she could not do so; because Ms. Stevens in no way represented that the decks did not exist, or that she could not obtain them, there was simply no concealment. Thus, the government has failed to prove that Ms. Stevens "concealed" the slide decks simply by preserving them in her files rather than voluntarily providing them to FDA.

B. The Government Has Not Proven That Ms. Stevens Had Any Corrupt Intent

Second, the government has not proved that Ms. Stevens intended to obstruct the FDA's investigation. The government must prove that Ms. Stevens acted with specific corrupt intent. To prove a "corrupt" violation, the government must prove "that the obstruction, or attempted obstruction, be done corruptly . . . with the bad purpose of accomplishing either an unlawful end or result, or a lawful end or result by some unlawful method or means." *United States v. Church*, 11 F. App'x 264, 268 (4th Cir. 2001) (quoting H.R. Rep. No. 681(I), 101st Cong., 2d Sess., 174 n.5, *reprinted in* U.S.C.C.A.N. 6472, 6580).[2]

[2] Accordingly, this Court's draft jury instruction on the mens rea for Count One (modifying the parties' Joint Proposed Jury Instruction No. 28 (ECF No. 158)) defines "corruptly" as meaning "that the defendant knowingly and willfully acted with consciousness of wrongdoing, that is, with the improper purpose of wrongfully obstructing,

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Intent admittedly can be established through circumstantial evidence. When, however, there are innocent explanations for a defendant's conduct, the government has the burden of negating them. *United States v. Law*, 528 F.3d 888, 896 (D.C. Cir. 2008). With regard to intent, as with other elements of a crime, all possible inferences from the facts should not be granted to the government; only those that are reasonable need be granted. *See Evans-Smith*, 19 F.3d at 908 n.22; *accord, United States v. Gen. Elec. Co.*, 869 F. Supp. 1285, 1290 (S.D. Ohio 1994) (the court need not "blindly and uncritically accept that every inference the prosecution argues can reasonably be drawn from the circumstantial evidence in the record").

In this case, the government has offered insufficient evidence of Ms. Stevens' intent. The government's case hinges primarily on the so-called "Pro-Con Memo," drafted by GSK's outside legal counsel at King & Spalding and provided to the internal GSK legal team. Govt. Ex. 8; *see* Tr. at. 38:2-43:25 (Testimony of J. Lemieux, Apr. 29, 2011). Yet this memo, from a reputable outside law firm to Ms. Stevens and GSK's legal team, does not establish that Ms. Stevens acted with the requisite corrupt intent. Nowhere does the memo indicate that GSK was legally required to provide the decks to FDA (whether or not they may have been potentially "incriminating"). Indeed, the fact that Ms. Stevens received a memo from a reputable law firm, authored by a prominent former FDA litigation counsel, weighing whether or not to produce the decks, demonstrates that the opposite was true: Ms. Stevens was advised by counsel that she did have a choice about whether and when to produce the decks.[3] Furthermore, Ms. Stevens was

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influencing, or impeding an official proceeding." ECF No. 181, at 65; *cf.* Mar. 23, 2011 Mem. Op. at 5 (ECF No. 132) (noting that the parallel *mens rea* for § 1519, "clearly requires consciousness of wrongdoing," *i.e.*, "the same sinister mentality which 'corruptly' requires" under § 1512) (quoting *United States v. Moyer*, 726 F. Supp. 2d 498, 506 (M.D. Pa. 2010)).

[3] The government appears to suggest that the designation of some documents as "privileged" is in itself a sign of corrupt intent. *E.g.*, Tr. at 39:13-16 (Testimony of J. Lemieux, Apr. 29, 2011) ("Q: Was it your understanding at the time that this would be privileged and not go outside of GSK and its counsel? A: Yes."); Tr. at 54:3-6 (Testimony of J. Lemieux, Apr. 29, 2011) ("Q: And during this time period did you have an understanding that

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specifically advised by Mark Brown of King & Spalding not to produce the decks until she was able to meet with FDA and provide additional context. Govt. Ex. 102-070 (Hetzel 3/18/03 notes: "M. Brown – should NOT produce these presentations"). Mr. Brown further advised her that she should not mention the presentations in the May letter to FDA. Govt. Ex. 102-079 (Hetzel 5/13/03 notes: "MB – would prefer not to mention doctors' presentation in the letter --> let FDA come back to GSK on this issue"). Where a defendant relies in good faith on the advice of informed counsel, she lacks the wrongful intent necessary for a criminal conviction. *United States v. Miller*, 658 F.2d 235, 237 (4th Cir. 1981) (stating that the reliance defense "is designed to refute the government's proof that the defendant intended to commit the offense").[4]

The government also attempts to rely on Ms. Stevens' handwritten notes to prove corrupt intent. But, like the memo, Ms. Stevens' notes show only that she was weighing whether and when to produce the decks. They do not support the conclusion that Ms. Stevens believed that she was legally required to produce the decks. Govt. Ex. 10-140 (Stevens 3/5/03 notes: "Presentations from physicians – pros / cons"); Govt. Ex. 10-151 (Stevens 4/3/03 notes: "Re: to give/not to give Prez"); Govt. Ex. 10-151 (Stevens 4/3/03 notes: "what we did not provide →

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these documents would be shared only among King and Spalding and GSK? A: Yes."); Tr. at 157:22-158:7 (Testimony of J. Lemieux, Apr. 29, 2011) (describing instructions to mark materials privileged). In fact, far from being evidence of corrupt intent, the "privileged" designation indicates that the communications reflect advice of counsel – a circumstance that in itself negates intent.

[4] The government has not established that King & Spalding was anything other than fully informed of the relevant facts at the time. With respect to the specific advice not to produce the slide decks, the record is indisputable that King & Spalding was fully informed. King & Spalding received and analyzed the decks themselves. *See* Govt. Ex. 193. The Pro-Con Memo itself proves beyond any doubt that King & Spalding received the decks and considered them in formulating the advice. *See* Govt. Ex. 8. With respect to the FDA's inquiry in general, the record is clear that King & Spalding received and reviewed voluminous materials. *See, e.g.,* Tr. at 93:9-95:13 (Testimony of J. Lemieux, May 3, 2011 (morning)) (describing how many letters had been sent to King & Spalding and noting that they may have received documents beyond what she tracked). Indeed, Julie Lemieux testified that the legal team had weekly meetings with King and Spalding and that they were sent extensive information over the course of many months. *Id.*; Tr. at 205:22-206:6 (Testimony of J. Lemieux, Apr. 28, 2011). Ms. Lemieux had no memory "one way or the other" on whether she provided some immaterial pieces of information to King & Spalding. Tr. at 167:4-6 (Testimony of J. Lemieux, Apr. 29, 2011) ("Q. And you have no recollection of ever sending them to the King and Spalding? A. I don't have memory one way or the other."); Tr. at 173:8-17 (Testimony of J. Lemieux, Apr 29, 2011) (affirming that her list of documents was her working list of her own files).

presentations – why? → off-label → voluntary"). Rather, the continuing deliberations, combined with King & Spalding's advice in the matter, demonstrate that Ms. Stevens believed that she had a lawful choice regarding whether to produce the decks at that time, and that she made that choice in the exercise of her legal judgment as GSK's lawyer, based on the advice of GSK's retained outside counsel.

No notes or emails show anyone on the legal team (from either GSK or King & Spalding) advising Ms. Stevens that GSK had to provide the slide decks, or that failure to do so would violate the law. (Notably, this team included Doug Snyder, another former FDA attorney, and Sherrie Shade, a former DDMAC reviewer.)

Finally, the fact that Ms. Stevens actively and repeatedly sought a meeting with FDA strongly argues against any corrupt intent. The documents illustrate that she fully expected the slide decks to be discussed at such a meeting. *See* Govt. Ex. 10-150 (Stevens 4/02/03 notes: "make request to meet + make prez - ? in context we want to present"); Def. Ex. 200 (6/5/03 Email from L. Stevens to GSK/K&S: "Rebecca Williams responded to my voicemail to her requesting a teleconference to discuss our submissions on the Wellbutrin matter . . . They will plan to follow up with us as they have additional questions or if there is anything else they need to talk to us about"). Indeed, King & Spalding began drafting a set of talking points to use at the anticipated meeting with FDA – and the first topic on the memo was the slide decks. Govt. Ex. 12 (King & Spalding draft of points to make in FDA conference call on slide decks). Ultimately, Ms. Stevens stopped calling, after numerous attempts, when FDA failed to engage.

Thus, voluminous evidence of advice of counsel and good-faith discussions demonstrates Ms. Stevens' innocent intent. In the face of this, the government offers a handful of de-contextualized notes, and one memo from outside counsel that Ms. Stevens did not draft. No

fact finder could reasonably draw an inference of criminal intent, beyond a reasonable doubt, from this scant evidence.

II. The Government Has Not Presented Evidence Sufficient to Show that Ms. Stevens Violated 18 U.S.C. § 1519 by "Falsifying" Documents or "Concealing" Information

The government has also charged that Ms. Stevens obstructed justice under 18 U.S.C. § 1519. Specifically, the indictment alleges that Ms. Stevens "sent false letters, falsified and altered documents, and concealed and covered up evidence of promotional activities including gifts and entertainment by GSK." Indict., p. 14. The apparent factual predicate for these charges is the deletion of an activities column in the spreadsheet of P.R.I.D.E. speaker programs that GSK created for and provided to FDA, and statements in the March 28, 2003 letter accompanying that spreadsheet.

The government's attempt to shoehorn this conduct into the language of the statute fails for several reasons: no information was "concealed"; no document was "falsified"; the letter sent with the spreadsheet was not false (as explained in Section IVB, below); and the government has not produced sufficient evidence of any corrupt intent by Ms. Stevens.

In order to establish that a defendant has "falsified" documents under § 1519, the government must prove, at a minimum, that the resulting documents were – in some way – *false*. "[T]here is nothing ambiguous or unclear about the word 'false'" in the statute, *United States v. Hunt*, 526 F.3d 739, 743 (11th Cir. 2008), and the case law is replete with examples. *See, e.g.*, *United States v. Fontenot,* 611 F.3d 734, 735-36 (11th Cir. 2010), *cert. denied*, 131 S.Ct. 1601 (corrections officer wrote false report of prison altercation, stating he followed state procedures and that prisoner attacked him, when officer had in fact violated procedures and initiated the attack); *Hunt*, 526 F.3d at 744 (police officer made false statement in incident report, stating suspect grabbed him first when, in fact, officer had initiated contact); *United States v. Jensen*,

248 F. App'x 849, 850 (10th Cir. 2007) (prison employee completed official paperwork falsely stating the inmate had provided a urine sample in his presence when in fact employee had given inmate a clean urine sample to use for drug test); *Moyer*, 726 F. Supp. 2d at 501-02 (M.D. Pa. 2010) (police officers falsely characterized witness accounts in official reports).

Here, however, the Government has offered no evidence from which a reasonable jury could conclude that the PRIDE database was indeed "false," *i.e.*, not true or correct. The government alleges that the spreadsheet of P.R.I.D.E Speaker Events produced with the March 28, 2003 letter was somehow "falsified" because it did not contain a column listing the entertainment provided at those events.

The spreadsheet is not "false" in the sense that it purports to be a more complete document than it is. To the contrary, the February 28, 2003 letter from GSK told FDA that the spreadsheet would provide "databases listing all speaker events including the date, location, speaker, and where available, the number of attendees." Govt. Ex. 2H, p. 7. The March 28, 2003, letter further clarified that "GSK specifically created these spreadsheets in response to FDA's request for information." Govt. Ex. 2I, p. 1. Thus, the legal team provided FDA with exactly what they promised: information about "date, location, speaker, and . . . number of attendees." *See* Tr. at 154:4-5, *see also* 33:11-14, 35:5-21 (Testimony of J. Lemieux, May 3, 2011 (morning)) (GSK informed FDA that they made spreadsheets to provide the information they had promised). The letters made no representation that any and all information about entertainment activities would be included.

Nor is the spreadsheet "false" in that sense that it contains inaccurate information. The government has not presented any evidence to show that the information in the spreadsheet sent to FDA is not correct. Given that the P.R.I.D.E. spreadsheet was an accurate document that

provided the information it purported to provide, the spreadsheet was in no sense "false" or "falsified."

Similarly, the spreadsheets do not "conceal" any information. They provide the information that GSK explicitly offered in the February letter. Notably, this information was offered voluntarily in response to an FDA Inquiry Letter, not under compulsion in response to a subpoena. In the absence of any duty to produce, or a representation that she was doing so, Ms. Stevens' omission of entertainment activities cannot be concealment.[5] *See* authorities cited *supra* at 5-7.

In order to obtain a conviction on Count II, the government must also prove that Ms. Stevens believed her actions were wrongful. The same "evil intent" required by 18 U.S.C. § 1512 is also required by § 1519. *See* Docket No. 132 (Mem. Op., March 23, 2011), at 5 (quoting *Moyer*, 726 F. Supp. 2d at 506). Where a defendant relies on the advice of counsel, that reliance negates the element of wrongful intent. *See id.* at 13-15 (citing, *inter alia*, *United States v. Peterson*, 101 F.3d 375, 381 (5th Cir. 1996) and *Miller*, 658 F.2d at 237).

Here, the government has not provided any evidence to prove that Ms. Stevens acted with a corrupt or wrongful intent. The only notes relating to entertainment reflect that, at a team meeting with King & Spalding, it was agreed that information about "entertainment" should not be included in the spreadsheet. Govt. Ex. 102-049 (Hetzel's 1/15/03 notes: "Do we want to keep entertainment column in PRIDE printout? General agreement that this info should be deleted.") To establish intent, therefore, the government relies on a tenuous chain of inferences derived

[5] By the same token, failure to include speaker compensation and the names of sales representatives in the spreadsheet is neither concealment nor falsification. The team made clear that they were not providing those items in the spreadsheet and in no way pretended that they had. The team did provide a schedule of speaker compensation with the November 14, 2002 letter to FDA. Govt. Ex. 2F-A-012.

from passing references to OIG in Ms. Stevens' notes.[6] The court need not credit such unsupported inferences in deciding a motion for acquittal; inferences must be reasonably drawn from the evidence. *See United States v. Souder,* 666 F. Supp. 2d 534, 549 (M.D.N.C. 2009) (refusing to draw an inference of intent to defraud where the government failed to present substantial evidence of any material misrepresentation).

Moreover, the notes and testimony clearly reflect the involvement of GSK's outside counsel in the decision. Like the GSK team, King & Spalding reviewed the inquiry letter from FDA (which nowhere used the word "entertainment"). *See* Govt. Ex. 1 (10/9/02 inquiry letter from FDA). King & Spalding reviewed the entertainment information that was ultimately not included in the spreadsheet produced to FDA. They fully participated in conversations regarding the speaker event spreadsheets. *See, e.g.*, Govt. Ex. 102-066, 72 (Hetzel's notes from 3/18/03 and 3/26/03 teleconferences with GSK and K&S discussing speaker event spreadsheets). And ultimately, they drafted the letter that accompanied and commented on the spreadsheets. Def. Ex. 18.001 (3/11/03 N. Reeves "forwarding an initial draft of the narrative to accompany the Wellbutrin speaker events databases" to GSK); 18.010 and 18.013 (3/18/03 and 3/21/03 M. Jensen sending a "revised narrative regarding the PRIDE and SE databases"); 18.026 (3/26/03 M. Jensen sending the final version to GSK). At no point did King & Spalding advise Ms. Stevens that failing to provide information about the entertainment offered at speaker programs would wrongfully obstruct the FDA's investigation. In these circumstances, the fact finder could not reasonably infer that Ms. Stevens possessed the requisite corrupt intent.

[6] Four such mentions of OIG occurred directly after the October 9, 2002 FDA Inquiry Letter and reflect preliminary thoughts of the investigation. One such mention is attributed to Doug Snyder, not Ms. Stevens. When the notes were taken, the core legal team had not been fully assembled and had not begun its investigation. One other reference to OIG, "more Cos going in light of OIG, Neurontin – either use Co. material or telling docs," lacks any context. *See* Gov. Ex. 10A-031.

For all these reasons, Count II should be dismissed.

III. Ms. Stevens Falls Within the § 1515(c) Safe Harbor for Lawful, *Bona Fide* Legal Representation

Finally, with respect to Counts I and II, Ms. Stevens is entitled to the protection of Section 1515(c)'s safe harbor, which provides that the obstruction statutes cannot be used to punish a defendant-lawyer's provision of lawful, *bona fide* legal representation services. Under the statute, "one who is performing bona fide legal representation does not have an improper purpose. His purpose – to zealously represent his client – is fully protected by the law." *United States v. Kloess,* 251 F.3d 941, 948 (11th Cir. 2001). In such a circumstance, the obstruction statutes do not apply. 18 U.S.C. § 1515(c) ("This chapter does not prohibit or punish the providing of lawful, *bona fide*, legal representation services in connection with or anticipation of an official proceeding.").

To raise § 1515(c)'s safe harbor, a defendant-lawyer need only show that she is "a licensed attorney who was validly retained to perform the legal representation which constitutes the charged conduct." *Kloess*, 251 F.3d at 948. This "minimal" showing, *id.*, which is not seriously disputed in this case, "is sufficient to raise an inference of innocent purpose." *Id.* Once the safe harbor has been raised by the defense, the government then bears the burden to prove beyond a reasonable doubt that the defendant's conduct "did not constitute lawful, *bona fide* legal representation." *Id.* at 949; *see id.* at 947-48 (where defendant invokes defense that negates the mental element of the offense, government bears the burden of proof beyond a reasonable doubt). "Having fairly raised the Section 1515(c) defense to culpability under Section 1512 . . . , the defendant is entitled to an acquittal unless the jury finds that the government proved beyond a reasonable doubt that the defendant's conduct did not constitute lawful, bona fide legal representation." *Id.* at 949.

Here, Ms. Stevens, an in-house corporate attorney engaged in her job of representing the Company in response to an FDA inquiry, has shown she is entitled to the protection of Section 1515(c). Because the Section 1515(c) defense has been fairly raised by Ms. Stevens, she is entitled to acquittal unless the government has proved beyond a reasonable doubt that her leadership in response to the FDA inquiry in 2002 and 2003 did not constitute lawful, *bona fide* legal representation. *See Kloess*, 251 F.3d at 949.

The government has failed to adduce evidence that would allow any reasonable fact finder to conclude beyond a reasonable doubt that Ms. Stevens was not engaged in lawful, *bona fide* legal representation. Even if the evidence presented to date were sufficient to sustain a verdict (which it is not), such proof by itself is insufficient to overcome the protection provided by the safe harbor. Any other conclusion would mean that the statutory safe harbor would add no protection for a lawyer's conscientious and zealous representation of her client.[7] More is required.

As this Court indicated preliminarily in comments from the bench, to fall outside § 1515(c)'s safe harbor, a lawyer's *representation* of her client must be a sham, or undertaken for an unlawful purpose. *See* 3/3/11 Hearing, Tr. p. 7 ("[I]f you go back to the movie *The Godfather*, the famous character played by Robert Duvall was clearly not, other than the fact that he had a law license, he was helping the Godfather commit crimes. And that is not *bona fide* legal advice, that's a crime.") Indeed, it is no surprise that courts that have rejected the § 1515(c) safe harbor based on non-*bona fide* representation have done so where the entire representation was undertaken for a criminal or fraudulent purpose. *See, e.g., United States v. Mintmire*, 507

[7] In passing § 1515(c), Congress noted that "the Subcommittee on Criminal Justice has received complaints of prosecutor's harassing members of the defense bar" and that "[v]igorously and zealously representing a client . . . is not a basis for charging an offense under the obstruction of justice chapter." *See* 132 Cong. Rec. 32,805 (1986).

F.3d 1273, 1294 n.21 (11th Cir. 2007) (expressing doubt that defendant was engaged in *bona fide* representation where he hired himself to represent a company he himself had created that was subject to investigation because of his own actions); *Crawford v. United States*, Nos. 04-71543 & 93-80202, 2008 WL 2948055, at *4 (E.D. Mich. July 31, 2008) (defendant was not engaged in bona fide legal representation services when he conspired with client and others in locating and killing a government witness); *cf. United States v. Cintolo*, 818 F.2d 980, 995-96 (1st Cir. 1987) (pre-§ 1515(c) obstruction case under § 1503; First Circuit rejected defendant attorney's claim of safe harbor for legal representation where defendant, retained by organized crime boss, conspired to have his client held in contempt and imprisoned to keep him from testifying against crime family's interests).

The circumstances of this case are far, far afield from those in the cases above. There was nothing sham or illegal about Ms. Stevens' representation of GSK in response to the FDA's inquiry. Ms. Stevens, an associate general counsel of GSK, was tasked by GSK's legal department with leading the company's response to the FDA, and she did so, heading a response team of three in-house attorneys and a retained outside law firm. This representation was ordinary and above board; it was lawful and *bona fide* in every sense. Ms. Stevens' actions in this case—receiving the FDA's inquiry, assembling a response team, defining and negotiating the scope of the inquiry, leading the investigation, gathering the facts, soliciting inside and outside advice, weighing that advice, exercising legal judgment and responding to the inquiring agency—were, simply put, what corporate counsel do. Moreover, the evidence makes clear that Ms. Stevens' purpose was not to enable some Company program to promote Wellbutrin off-label – to the contrary, she consistently remediated problems where she found them.

Though the government now contends that some statements in the course of her advocacy were false, or that documents were not turned over that should have been, these are the sorts of disputes that arise when a lawyer vigorously defends her client and takes positions with which equally zealous government investigators disagree. The role of the lawyer is to defend her client, to minimize her client's exposure, to press for advantage where possible, to seek advice where advisable, and to exercise judgment in doing so. It is to protect this exercise of judgment, and of zealous advocacy, that the § 1515(c) safe harbor exists. To overcome that harbor the government must do more than it has here. It must prove that the *representation* was a sham, undertaken for criminal rather than genuine purposes.

The government has not come close to making such a showing here. Therefore, this Court should enter a judgment of acquittal on the two counts charging obstruction of justice.

IV. The Government Has Not Proven That Ms. Stevens Made Any False Statements to FDA

To return a conviction on 18 U.S.C. § 1001, the jury must be convinced beyond a reasonable doubt "(1) that the defendant made a false statement to a governmental agency or concealed a fact from it or used a false document knowing it to be false; (2) the defendant acted knowingly or willfully; and (3) the false statement or concealed fact or false document was material to a matter within the jurisdiction of the agency." *United States v. Sarihifard*, 155 F.3d 301, 306 (4th Cir. 1998). The Government has not proven any of these elements with regard to the charged statements.

A. The Statements Regarding Advisory Boards in the February 28, 2003 Letter Were Not Material, Intentional Falsehoods.

The government has failed to prove that the statement regarding advisory boards charged in Count III was either material or intentionally false. That count is based on the statement that "GSK has two types of advisory boards – National Advisory Boards and Local Advisory Boards

. . . Pursuant to GSK policy, no sales region may have more than two Local Advisory Boards, and no such board may meet more than twice per year." Indict., p. 15. The government has alleged that the omission of Special Issue Boards (SIBs) renders this a false statement. The statement regarding advisory boards was, however, according to the government's FDA witness, immaterial to the FDA. Furthermore, the omission of SIBs resulted from simple oversight, not from an intent to lie.

The government has failed to prove materiality. A statement is material if it has the tendency to influence the decision of the decision-making body to which it was addressed. *United States v. Benkahla*, 530 F.3d 300, 310 (4th Cir. 2008). The government's own witness, Sonny Saini, stated that the FDA was not interested in advisory boards at the time of the letter. Tr. at 55:7-14 (Testimony of S. Saini, Apr. 27, 2011) (stating that in 2002-2003, the FDA was not interested in advisory boards). FDA asked, however, only for a general understanding of advisory boards, not for the number of boards actually held; thus, there is no reason to believe that a general description of SIBs would have been material. Nor has the government produced any evidence that suggests that the SIBs were being used for any unlawful purpose. Thus, the statements at issue were not material.

Finally, the government has not proven intent. To knowingly and willfully make a false statement or conceal a fact, a defendant must act with bad purpose either to disobey or disregard the law. *United States v. Seay*, 718 F.2d 1279, 1284 (4th Cir. 1983). "[T]he word knowingly is in the statute to ensure that no defendant is convicted for making a statement that was false because of some mistake or accident." *Id.* Here, the government has offered no evidence of bad purpose. Rather, the evidence shows that the statement charged was drafted by GSK's outside counsel, King & Spalding, and that throughout the drafting process no one reviewing the drafts

noted that SIBs were not mentioned. Tr. at 228:24-229:14 (Testimony of J. Lemieux, Apr. 29, 2011) (King & Spalding had all GSK policies); Tr. at 117:2-120:2 (Testimony of J. Lemieux, May 3, 2011) (draft of letter on section on advisory boards came from King & Spalding). *E.g.*, Govt. Ex. 111 (correspondence with drafts of letter, showing no changes to advisory board portion of letter); Def. Ex. 17.98 (same). Ms. Stevens' lack of intent is further demonstrated by the fact that the April 28, 2003 letter mentions a SIB. Govt. Ex. 2J. The government has pointed to no evidence that the omission of SIBs is anything other than simple mistake.

B. The Statement Regarding Attendee Compensation in the March 28, 2003 Letter Is Not False

In Count IV, the government charges Ms. Stevens with making a false statement in GSK's March 28, 2003 letter. Specifically, the letter states: "Attendees were not paid, reimbursed, or otherwise compensated to attend these events, with the exception of reimbursement for parking fees in some cases." Indict., p. 17. The government further alleges that Ms. Stevens knew this statement was false, because she knew that GSK had provided "gifts and entertainment" to attendees and had even removed this information from a version of a spreadsheet before sending it to the FDA. *Id*. Because the evidence in the government's case-in-chief has demonstrated that the statement is true, and because the government has failed to prove intent, Ms. Stevens should be acquitted as to Count IV.

The government has failed to prove that this statement is false through any evidence that attendees were in fact "compensated" for their attendance at any speaker events. No evidence suggests that attendees were paid. At best, the government has demonstrated that attendees (1) sometimes participated in an entertainment activity as a part of a speaking event (*see, e.g.*, Tr. at 66:3-66:10 (Testimony of J. Lemieux, Apr. 29, 2011) (referring to "a recreational activity or an entertainment column" in a speaker event spreadsheet)) and (2) could receive a medically

relevant gift at a P.R.I.D.E. program. Tr. at 135:6-136:17 (Testimony of J. Lemieux, Apr. 29, 2011). But the government has offered no evidence that such entertainment or gift was "compensation." Indeed, the term "compensation" is used elsewhere in the evidence only to refer to *payments* to speakers. Def. Ex. 7A at GSKCO-0155-003984 (standard fee schedule attached to November 14, 2002 letter); Def. Ex. 9 at GSKCO-0155-004255 (stating that GSK "did not compensate Dr. Anderson" but did reimburse his out-of-pocket expenses); *id.* at GSKCO-0155-004259 (describing the honorarium and travel stipend provided to Dr. Ryan for her participation on a panel and also saying Dr. Ryan "was not compensated by GSK" for her participation in clinical research). This understanding is consistent with the dictionary definition of "compensation" as "payment" or "remuneration." *Merriam-Webster's Collegiate Dictionary* 234 (10th ed. 2001).

Nor has the government offered any evidence at all that would support a reasonable inference that entertainment was in fact being offered as "remuneration," *i.e.*, as a quid pro quo for something. The court need not accept an unsupported inference that doctors were somehow "compensated" by the entertainment component of the programs they attended. *See United States v. Grow*, 394 F.2d 182, 199 (4th Cir. 1968) ("An inference is a logical deduction or conclusion from established fact. . . . When the first or basic inference is impermissibly drawn it cannot therefore serve to support other inferences upon which a subsequent finding is based."); *Souder,* 666 F. Supp. 2d at 549 (holding that the government failed to present substantial evidence of any material misrepresentation or omission perpetrated by defendants when describing an insurance policy to members of a fraternal organization on which to base a reasonable inference that they acted with specific intent to defraud); *United States v. McGavock*, 2005 U.S. Dist. LEXIS 24615 (W.D. Va. Oct. 18, 2005)(affirming judgment of acquittal for a

reckless driving charge since the mere happening of an accident does not give rise to an inference of reckless driving).

Even if the court were to draw every conceivable inference in favor of the government (which it need not do), the statement regarding compensation would be at most ambiguous. Were the statement ambiguous, the government would bear the burden of negating the reasonable interpretation that "compensation" refers to money paid to an attendee (for instance, in the form of an honorarium). *United States v. Race*, 632 F.2d 1114, 1120 (4th Cir. 1980); *United States v. Barsanti*, 943 F.2d 428, 432 (4th Cir. 1991); *United States v. Baer*, 274 F. Supp. 2d 778, 781 (E.D. Va. 2003). The government has not provided any evidence that would negate the reasonable interpretation of "compensation" evidently adopted by the team.

The government has also failed to demonstrate that Ms. Stevens believed the statement to be false. Because making a false statement is a specific-intent crime, a good faith belief that the statement is true serves as a complete defense. *United States v. Young*, 470 U.S. 1, 32 (1985). In this case, the government has failed to introduce any evidence of wrongful intent. The government appears to rely solely on the fact that Ms. Stevens and the legal team decided not to provide information regarding entertainment in a spreadsheet to FDA. Tr. at 140:16-141:18 (Testimony of J. Lemieux, Apr. 29, 2011) (agreeing that activities column is still in spreadsheet and that Ms. Stevens was to delete it); *id.* at 148:14-149:9 (acknowledging that the activities column was no longer present in the spreadsheet sent to FDA). But this fact provides no insight whatsoever into whether Ms. Stevens believed that "entertainment" was the same thing as "compensation."

Indeed, the evidence suggests exactly the opposite. None of the voluminous notes produced in this case reflect any comment that "entertainment" was in fact the same thing as

"compensation." King & Spalding, upon whom Ms. Stevens relied for advice, drafted the March letter after reviewing all of the information regarding speaker entertainment. Govt. Ex. 102-066, 72 (Hetzel's notes from 3/18/03 and 3/26/03 teleconferences with GSK and K&S discussing speaker event spreadsheets); Def. Ex. 18.001 (N. Reeves 3/11/03 email "forwarding an initial draft of the narrative to accompany the Wellbutrin speaker events databases" to GSK); 18.010 and 18.013 (M. Jensen's 3/18/03 and 3/21/03 emails sending a "revised narrative regarding the PRIDE and SE databases"); 18.026 (M. Jensen's 3/26/03 email sending the final version to GSK) Indeed, after reviewing the entertainment information, King & Spalding sent GSK a draft letter saying "Attendees were not paid, reimbursed, or otherwise compensated to attend these events. **[confirm]**" Def. Ex. 18.001. The note to "confirm" would be nonsensical if in fact the team understood the entertainment activities, of which they were all fully aware, to be "compensation." In light of this evidence, one cannot reasonably draw an inference that Ms. Stevens (or anyone else on the team) understood "entertainment" to fit within the overly broad definition of "compensation" proffered by the government. Ms. Stevens must therefore be acquitted on Count IV.

C. The Conclusions Stated in the February, May, and November Letters Are Not False

Last, in Counts III, V, and VI, the government alleges that a series of conclusions stated in the February, May, and November letters constitute false statements. The gist of all these statements is, as the May letter states, that "GSK has not developed, devised, established, or maintained any program or activity to promote, either directly or indirectly, the use of Wellbutrin SR to achieve weight loss or treat obesity." (Indict., p. 18; *see also* pp. 15-16, 20.) The government posits that these statements are knowingly false because, essentially, Ms. Stevens

knew that "GSK's paid speakers for Wellbutrin were presenting materials about unapproved uses" during GSK-sponsored events. (*Id.* at 16, 18-20.)

Ms. Stevens cannot be convicted on the basis of these statements, for two reasons: First, the government has not proven that the statements are false, given that a reasonable interpretation exists under which the statements are true. Second, and relatedly, the government has failed to prove that Ms. Stevens acted with a specific intent to make a false or fraudulent statement, as required by the statute. *See United States v. Herron*, 521 F. Supp. 928, 931 (D.S.C. 1981) (examining § 1001 and noting that the defendant must act willfully with specific intent); *United States v. Lange*, 528 F.2d 1280, 1288 (5th Cir. 1976) ("A violation of § 1001 requires proof that the defendant had the specific intent to make a false or fraudulent statement.").

The falsity of the statements hinges, of course, on the interpretation given to the statements. Where, as here, a charged statement is true under a "reasonable construction" of the language, the Government must "negativ[e] any reasonable interpretation that would make the defendant's statement factually correct"; where the government fails to do so, "a conviction under § 1001 cannot stand." *United States v. Race*, 632 F.2d 1114, 1120 (4th Cir. 1980); *see also United States v. Baer*, 274 F. Supp. 2d 778 (E.D. Va. 2003) (holding that where defendant's answer to a question on an application was true under a reasonable construction of the question, he could not be convicted of making a false statement).

The government suggests that the statements in question are an outright denial of any off-label activity with regard to Wellbutrin. But the government's proffered gloss on the statements is contradicted by the letters themselves. At the same time that the letters conclude that GSK "has not engaged in the promotion of Wellbutrin SR for weight loss" (Govt. Ex. 2K), they also frankly admitted a variety of missteps:

- The December 23, 2002 letter admits that GSK inadvertently provided its speaker trainees with an off-label slide deck at certain trainings. Govt. Ex. 2G.
- The March 28, 2003 letter admits that approximately 75 speaker presentations over the past two years had off-label topics. Govt. Ex. 2I.
- The April 28, 2003 letter admits that Dr. Wolkowitz, a promotional speaker for GSK, used a presentation that "contained phrases and information about the effect of Wellbutrin SR on body weight that some may consider as outside the product's approved indication." Govt. Ex. 2J. Further, the letter admits that this was his standard presentation and that he had spoken 49 times during the relevant time period. *Id.*
- The May 21, 2003 letter admits that "[i]n the course of responding to your requests, we became aware of certain activities that were inconsistent with GSK policies. Rather than attempt to justify these activities, the Company took its responsibilities seriously and instituted appropriate and necessary corrective actions to address these activities." Govt. Ex. 2K.
- The November 6, 2003 letter admits, among other things, that in the process of responding to FDA, the GSK team "became aware of some activities that were inconsistent with GSK policy, including certain presentation topics and presentations delivered by physician speakers that contained information outside the approved product labeling." Govt. Ex. 2L-001. The letter also disclosed that, in the spring of 2002, "Dr. Hudziak was using inappropriate materials in his slide presentations." *Id.* at 003.

The conclusions regarding GSK's promotional activities must be read in light of these contemporaneous admissions. *See, e.g.*, *United States v. Juncal*, 245 F.3d 166, 172-73 (2d Cir. 2001) (holding a two-level enhancement for obstruction of justice based on an allegedly perjurious affidavit unwarranted where the defendant's truthful statements via affidavit had not been "read as a whole" and "viewed in light of the details . . . that accompanied them"); *United States v. Markiewicz*, 978 F.2d 786, 808 (2d Cir. 1992) (viewing questions and testimony at civil deposition "as a whole" to determine whether statement was perjurious); *United States v. Schafrick*, 871 F.2d 300, 303 (2d Cir. 1989) (holding that to determine whether statements are perjurious, they "must be judged according to common sense standards and given their natural meaning in relation to their context").

A reasonable interpretation of the statements in context is that the Company did not have a *plan* to promote off-label, even though certain off-label promotional activities did take place. In order to arrive at a contrary interpretation, a fact-finder would have to look at the charged statements in isolation, disregarding all other evidence. Although reasonable inferences are to be made in the government's favor on a Rule 29 motion, the court need not accept interpretations and inferences that are "unreasonable, insupportable, or overly speculative." *United States v. Woodward*, 149 F.3d 56-57 (1st Cir. 1998). "'[A]n inference is not reasonable if it is only a guess or a possibility, for such an inference is not based on the evidence but is pure conjecture and speculation.'" *United States v. Lentz*, 383 F.3d 191, 226 (4th Cir. 2004) (Michael, J., dissenting) (quoting *Daniels v. Twin Oaks Nursing Home*, 692 F.2d 1321, 1324 (11th Cir. 1982)). In this case, the government has presented no evidence to negative the reasonable interpretation suggested by the text of the letters themselves.

Under this reasonable interpretation, furthermore, the statements are true: the Company did have an on-label promotional policy. Its speaker agreements required promotional speakers to remain on-label. *See, e.g.* Govt. Ex. 2F-A at GSKCO-0155-003985 (speaker agreement); Govt. Ex. 2F-A at GSKCO-0155-003990 (same); Govt. Ex. 2F-B at GSKCO-0155-004153 (same); Govt. Ex. 2F-B at GSKCO-0155-004156 (same). The evidence illustrates that Ms. Stevens and others in the legal department enforced these requirements. For instance, in response to a question regarding Dr. Hudziak in spring 2002, Ms. Stevens advised that speakers must stay on label. Govt. Ex. 33 (L. Stevens says "Hudziak must abide by his commitment" to stay on-label). The Company fired Matt Burke, a successful vice-president, after he forwarded an email praising an apparently off-label presentation. Testimony of C. Kelly, May 5, 2011.[8] Ms. Stevens herself required Wolkowitz to commit to remaining on-label and provided instruction on the requirements to insure that he did so. Def. Ex. 157.

The governments own witnesses further supported the idea that GSK's policy was that speakers must promote on label only. Mr. Millar confirmed specifically that GSK "never had a centrally developed orchestrated … intent to market the drug [Wellbutrin] for obesity." Tr. at 94:15-16 (Testimony of J. Millar, May 4, 2011 (afternoon)); *see also* Tr. at 94:13-95:13, 96:19-98:9 (Testimony of J. Millar, May 4, 2011 (afternoon)) (explaining why he believes there is no corporate policy to promote). Mr. Millar also described GSK as having a "culture of ethics." Tr. at 64:10-12 (Testimony of J. Millar, May 4, 2011 (afternoon)); *see also* Tr. at 67:23-68:22 (Testimony of J. Millar, May 4, 2011 (afternoon)) (describing GSK's policy to be a leader in ethics and compliance as a sincere corporate policy and agreeing that part of that came from Ms. Stevens); Tr. at 29:22-25 (Testimony of J. Millar, May 4, 2011 (morning)) (describing GSK as

[8] Transcripts for portions of May 5, 2011 and all of May 6, 2011 are not yet available.

"ahead of our peer companies" in terms of educating physicians on FDA regulations).[9] David Wheadon, Vice-President of Regulatory at GSK in 2002 and 2003, testified that he was not aware of any Company policy to promote Wellbutrin off-label for obesity. (Testimony of D. Wheadon, May 6, 2011.[10]) Dr. Wheadon also testified that GSK was an ethical company that took compliance with regulations, including with off-label regulations, very seriously. (Testimony of D. Wheadon, May 6, 2011.) Julie Lemieux testified that in 2002 and 2003, she was perfectly comfortable telling doctors that it was not GSK's policy to promote off-label. Tr. at 43:16-44:6 (Testimony of J. Lemieux, May 3, 2011 (morning)). Julie Lemieux testified that GSK took off-label promotion seriously. Tr. at 20:16-21:8 (Testimony of J. Lemieux, May 3, 2011 (morning). Moreover, Ms. Stevens heard similar reports from others in the Company during the relevant time period. Govt. Ex. 281 (King & Spalding summary of November 2002 interviews: "Prior to joining GSK as an employee, Modell periodically served as a GSK-sponsored speaker since at least 1995. He never felt pressure from a GSK sales rep to use WBSR for weight loss.") Tr. at 44:17-22 (Testimony of J. Millar, May 4, 2011 (afternoon)) (discussing statement from J. Modell in interview summary).

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[9] The evidence demonstrates that the Company consistently took action to quell off-label activities as they arose, supporting the logical inference that the Company had no program to promote off-label. *See* Govt. Ex. 12 at 6-7 (remedial actions listed in King & Spalding talking points memo); Govt. Ex. 30 (J. Millar email regarding Hudziak remediation); Govt. Ex. 35 (Hudziak counseling); Govt Ex. 40 (confirming Hudziak is using correct slides); Govt. Ex. 50 (J. Millar counsels Pradko); Govt. Ex. 55 (internal investigation into Burke forwarding May's notes); Govt. Ex. 56 (letter to Pradko with King & Spalding edits); Govt. Ex. 62 (J. Millar letter regarding Pradko needing to comply with GSK on-label requirements); Govt. Ex. 68 (remedial email sent to all recipients of Burke's email); Govt. Ex. 69B (L. Stevens letter to Dr. Pradko confirming his compliance with his speaker commitment); Govt Ex. 116 (L. Stevens works to address slide fulfillment concerns); Govt. Ex. 144 (L. Stevens removes speakers from speaker database if speaker did not sign letter re-committing to present on-label information); Govt. Ex. 152 (letter to doctors, drafted by King & Spalding, reminding them to speak on label); Govt Ex. 156 (L. Stevens email to Wolkowitz explaining laws and demanding that he stop using his slides); Govt. Ex. 202 (10/03 email trying to obtain physician slides); Govt. Ex. 247 (email from L. Stevens regarding obligation as a company to have speakers stay on label); Govt. Ex. 265 (L. Gonzalez report of coaching and counseling of sales reps with apparent off-label topics); Govt. Ex. 285 (draft of message to send to recipients of M. Burke email); Tr. at 72:20-73: 1 (Testimony of J. Millar, May 4, 2011 (afternoon)) (Burke was fired for violating the commercial practices policies).

[10] Transcripts for portions of May 5, 2011 and all of May 6, 2011 are not yet available.

The evidence regarding Drs. Pradko and Hudziak, the most prolific speakers on Wellbutrin, does not undermine this overall assessment of the Company's programs. The evidence demonstrates that, as to these doctors, the Company promptly corrected their use of unapproved content. Tr. at 85:20-86:5 (Testimony of J. Millar, May 4, 2011 (morning)) (describing remediation meeting with Dr. Pradko); Tr. 13:8-22:20 (Testimony of J. Millar, May 5, 2011) (morning)) (detailing Millar's face-to-face meeting with Dr. Hudziak and GSK's subsequent efforts to revise Dr. Hudziak's slides); *id.* at 22:21-26:5 (explaining that the corrective actions resulted in Dr. Hudziak speaking with the GSK approved slide deck). As Mr. Millar testified, the doctors' talks were objectionable primarily because both translated commonly accepted pharmacology into clinical utility. Tr. 52:3-15 (Testimony of J. Millar, May 5, 2011) (morning)). Moreover, neither doctor promoted Wellbutrin for weight loss. Tr. at 43:8-11 (Testimony of J. Millar, May 4, 2011 (morning)) ("I didn't have the sense that either doctor [Pradko or Hudziak] was a walking billboard, you know, saying Wellbutrin should be used in obesity."); Tr. 39:11-15 (Testimony of J. Millar, May 5, 2011 (morning)) ("It wasn't as if [Drs. Pradko and Hudziak] were, you know, walking billboards for bupropion in obesity.); Tr. 79:2-3 (Testimony of J. Millar, May 5, 2011) (morning)) (stating that Dr. Pradko was "[n]ot hawking. . . Wellbutrin as a diet pill.")

Nor has the government proven that, with regard to these conclusory statements, Ms. Stevens intended to lie. To the contrary, the statements were drafted by GSK's outside counsel, King & Spalding.[11] No one ever suggested to Ms. Stevens that the statements were false. Julie

[11] *E.g.*, Tr. at 130:4-24 (Testimony of J. Lemieux, May 3, 2011 (Feb. letter drafted by King & Spalding); Def. Ex. 17.016 (N. Reeves' 1/22/03 email to M. Brown and M. Jensen containing a revised narrative); Def. Ex. 17.020 (M. Brown's 1/23/03 email to GSK sending a draft response to Request No. 1, noting that K&S is in the process of drafting other responses); Def. Ex. 17.048 (N. Reeves' 2/5/03 email to M. Brown sending revised response to question 12); Def. Ex. 17-090 (M. Brown's 2/12/03 email, noting significant revisions to response to request no. 1); Def. Ex. 17-148 (M. Brown's 2/27/03 email sending "final response"); Def. Ex. 20.001 (M. Brown's 4/9/03 email (cont'd)

Lemieux, the paralegal on the team who attended all the team meetings, confirmed that no lawyer from either GSK or King & Spalding ever suggested that the conclusions stated in the February or May letters were false.[12] Tr. at 9:17-24 (Testimony of J. Lemieux, April 29, 2011); Tr. at 134:19-135:7 (Testimony of J. Lemieux, May 3, 2011). She herself believed the statements to be true. *Id.* at 155:4-9. Likewise, James Millar, the Wellbutrin Product Director who reviewed the letter, testified that he never advised the team that the statements were false; he further stated that "I would have laid down in the tracks and said … there's something wrong with that," had he thought the statements were misleading or false. Tr. at 99:6-7 (Testimony of J. Millar, May 5, 2011 (morning)).

Nor do the heavily edited and commented-upon drafts to the letters contain any evidence that Ms. Stevens – or anyone else on her team – ever suggested the letters were false or that the statements in question should even be revised. *See, e.g.,* Govt. Ex. 151 (draft of November 2003 letter with comments); Govt. Ex. 207 (same); Govt. Ex. 218 (comments on draft of February 2003 letter); Govt. Ex. 419 (comments on April 2003 letter). On this record, the government has failed to present sufficient evidence Ms. Stevens had the intent necessary for a conviction based on these statements.

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sending draft of supplemental response to Request No. 14 to GSK); Def. Ex. 20.005 (M. Brown's 4/9/03 email sending "revised version of response incorporating changes" discussed with GSK earlier); Def. Ex. 20.010 (M. Brown's 5/5/03 email to GSK sending a "new" draft response to FDA); Def. Ex. 20.017 (M. Brown's 5/9/03 email sending edited and revised drafts to GSK); Def. Ex. 20.026 (M. Brown's 5/13/03 email sending draft with "significant changes" to GSK); Def. Ex. 21.013 (M. Brown's 11/3/03 email to GSK sending "revised draft of letter," cutting out an entire page).

[12] The government has attempted to undermine Ms. Stevens' reliance on counsel through an email in which Mark Brown of King & Spalding noted that one proposed draft might be too "aggressive and up-tempo"; Ms. Stevens nonetheless stated that she preferred the wording in this draft. Tr. 149:15-152:14 (Testimony of J. Lemieux, 4/29/11). This email is irrelevant to the statements charged, however; while the "up-tempo" draft differed somewhat from the previous iteration of the letter, the statements at issue here appeared in both the "up-tempo" and more subdued version of the letter. *See* Ex. D-0020.16. In any case, King & Spalding drafted both versions, and never suggested that using one would be illegal.

CONCLUSION

For the reasons stated, Ms. Stevens, by counsel, respectfully requests that the Court grant defendant's motion for a judgment of acquittal. A proposed Order is attached.

Respectfully submitted,

Dated: May 8, 2011

By: /s/

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